UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

EUGENE DIVISION

BETTY PHELPS and DELBERT PHELPS, 09-CV-6168-TC

Plaintiffs,

v. FINDINGS AND RECOMMENDATION

WYETH, INC., et al.,

Defendants.

COFFIN, Magistrate Judge:

Plaintiffs bring this action alleging that Betty Phelps was injured after ingesting generic pharmaceutical products produced by defendants PLIVA USA, Inc. (Pliva) and Northstar Rx LLC (Northstar). I stayed this case pending the United States Supreme Court's decision in Pliva, Inc. et al. v. Mensing, 131 S. Ct. 2567, 2570 (2011) reh'g denied, No. 09-993, 2011 WL 3557247 (U.S. Aug. 15, 2011). The Supreme Court decided Mensing on June 23, 2011, holding that federal law preempts state laws that impose a duty upon generic manufacturers, like Pliva and Northstar, to

change the drug's label. Following a July 8, 2011 status conference, the parties filed supplemental motions - Northstar filed a motion for summary judgment, Pliva filed a motion to dismiss, and plaintiffs filed a motion for partial summary judgment. I heard oral arguments on these motions on September 15, 2011. In the minute order filed after the oral argument, I granted plaintiffs leave to file a motion to file an amended compliant. (#232). On November 22, 2011, I granted plaintiffs' motion to file an amended complaint, and plaintiffs filed their first amended complaint on the same day.[1] (#s 254, 255).

Background

The parties do not dispute the following facts. Metoclopramide is a prescription drug that is available in either generic or name-brand formulation. Reglan®, the brand name formulation, was produced at different times by defendants Wyeth, Schwarz, and Alaven. Pliva and Northstar, the only two defendants remaining in these proceedings, produced the generic formulation of metoclopramide.

Ms. Phelps took generic metoclopramide tablets from November 2002 through at least August 2009. She alleges that metoclopramide caused her to develop tardive dyskinesia, a debilitating neurological condition characterized by involuntary movements. She claims that the defendants, the generic manufacturers of metoclopramide, are liable for her injuries because they negligently failed to adequately warn her and her doctors about the risks associated with long-term use of metoclopramide.

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[1]The First Amended Complaint includes a specific allegation that generic manufacturer Pliva failed to update its warning label for its metoclopramide product when the FDA approved revisions to the label for Reglan/metoclopramide in 2003 and 2004. Otherwise, the claims in the First Amended Complaint remain the same as the claims in plaintiffs' original complaint.

Legal Standard

Federal Rule of Civil Procedure 56 allows the granting of summary judgment:

> if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.

Fed. R. Civ. P. 56(c). There must be no genuine issue of material fact. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986).

The movant has the initial burden of establishing that no genuine issue of material fact exists or that a material fact essential to the nonmovant's claim is missing. Celotex Corp. v. Catrett, 477 U.S. 317, 322-24 (1986). Once the movant has met its burden, the burden shifts to the nonmovant to produce specific evidence to establish a genuine issue of material fact or to establish the existence of all facts material to the claim. Id.; see also, Bhan v. NME Hosp., Inc., 929 F.2d 1404, 1409 (9th Cir. 1991); Nissan Fire & Marine Ins. Co., Ltd., v. Fritz Cos., Inc., 210 F.3d 1099, 1105 (9th Cir. 2000). In order to meet this burden, the nonmovant "may not rely merely on allegations or denials in its own pleading," but must instead "set out specific facts showing a genuine issue of fact for trial." Fed. R. Civ. P. 56(e).

Summary judgment is appropriate when federal law preempts a plaintiff's state law claims. See, e.g., Bank of Am. v. City & Cnty. of San Francisco, 309 F.3d 551, 566 (9th Cir. 2002) (affirming district court's decision to grant summary judgment based on federal conflict preemption). Similarly, when federal law preempts all claims in a complaint, dismissal for failure to state a claim is appropriate. See, e.g., Whistler Invs., Inc. v. Depository Trust & Clearing Corp., 539 F.3d 1159, 1163 (9th Cir. 2008) (affirming dismissal of claim based on federal conflict preemption).

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Discussion

In their original complaint, plaintiffs asserted a variety of claims against the defendants: (1) negligence (Count One); (2) strict liability (Count Two); (3) breach of warranties (Count Three); (4) misrepresentation and fraud (Count Four); and (5) gross negligence (Count Five). Each of these claims is based on plaintiffs' argument that Pliva and Northstar failed to exercise reasonable care in the marketing of generic metoclopramide because they failed to adequately warn Ms. Phelps and her doctors about the dangers of the drug.

Plaintiffs' claims can be distilled down to a claim of product liability. Oregon's product liability statute provides that:

> 'product liability in a civil action' means a civil action brought against a manufacturer, distributor, seller or lessor of a product for damages for personal injury...arising out of: (1) any design, inspection, testing, manufacturing or other defect in a product; (2) any failure to warn regarding a product; or (3) any failure to properly instruct in the use of a product.

ORS 30.900. Plaintiffs brought this action alleging Ms. Phelps' injury of tardive dyskinesia was caused by generic-brand manufacturer's inadequate warnings. Thus, this action falls within Oregon's definition of a product liability action.

Additionally, in their Supplemental Motion for Partial Summary Judgment plaintiffs seek summary judgment based on a theory of negligence per se, alleging that Pliva failed to comply with FDA regulations that require a generic manufacturer to update the warnings accompanying its drug products after changes are approved by the FDA for the corresponding brand-name drug. Plaintiffs claim that the FDA updated the warnings for Reglan®/metoclopramide in 2003 and 2004, and that Pliva failed to incorporate those changes for almost the entirety of the time Ms. Phelps consumed its drug. On November 22, 2011 plaintiffs filed their First Amended Complaint reflecting this claim.

Defendant Northstar's Motion for Summary Judgment

Defendant Northstar asserts that all of plaintiffs' claims against it are preempted by federal law. However, reaching this conclusion is unnecessary because the undisputed facts show that Ms. Phelps was diagnosed with tardive dyskinesia before she began ingesting Northstar's generic brand of metoclopramide. Well established Oregon law states that a manufacturer cannot be held liable unless and until the plaintiff proves that her injuries resulted from use of that manufacturer's product. McEwen v. Ortho Pharma. Corp., 270 Or. 375, 407 (1974)(discussing in a failure to warn case whether each defendants' negligence could be found to be a substantial cause of plaintiff's ingestion of the oral contraceptive manufactured by that defendant). "[N]egligence and strict products liability [claims] require the plaintiff prove a causal connection between the alleged negligence or defective product and the injuries sustained by the plaintiff." Glover v. BIC Corp., 6 F.3d 1318, 1327 (9th Cir. 1993). Plaintiffs have failed to show that Northstar's product substantially caused Ms. Phelps' condition. Therefore, I recommend that this court grant Northstar's motion for summary judgment.

Defendant Pliva's Motion to Dismiss

Like Northstar, defendant Pliva asserts that all of plaintiffs' claims against it are preempted by federal law. When federal law preempts all claims in a complaint, dismissal for failure to state a claim is appropriate. See, e.g., Whistler Investments, Inc. v. Depository Trust & Clearing Corp., 539 F.3d 1159, 1163 (9th Cir. 2008) (affirming dismissal of claim based on federal conflict preemption).

The Supremacy Clause establishes that federal law "shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. "Where state and federal law directly conflict, state law must give way." Mensing,

131 S. Ct. at 2570. State and federal law conflict where it is "impossible for a private party to comply with both state and federal requirements." Id. (citing 4 Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995)).

Federal regulations applicable to generic drug manufacturers directly conflict with, and thus preempt, state laws that hold generic drug manufacturers liable for inadequate warning labels on their products. Mensing, 131 S. Ct. at 2578. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate. 21 U.S.C. § 355(b)(1). By contrast, under the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Amendments, generic drug formulations can gain FDA approval by showing bioequivalence to a reference-listed drug that has already been approved by the FDA. 21 U.S.C. § 355(j)(2)(A). A generic drug application must also show that "the labeling proposed for the new drug is the same as the labeling approved for the listed drug." 21 U.S.C. § 355(j)(2)(A)(v). Therefore, rather than a duty to warn, "generic manufacturers have an ongoing federal duty of sameness" regarding their warning labels. Mensing, 131 S. Ct. at 2574. Under the same rules, generic drug manufacturers may not issue additional warnings through Dear Doctor letters, nor may they imply in any way that there is a therapeutic difference between their product and the name-brand drug. Id. at 2576.

In Mensing, the plaintiffs' claims were based on state laws that required a drug manufacturer that "is or should be aware of its product's danger to label that product in a way that renders it reasonably safe." Id. at 2573, 2577. In those states, the duty to warn fell specifically on the manufacturer, brand-name and generic alike. Id. at 2577. "Thus it was impossible for the

Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." Id. at 2578.

Similarly, in this case, plaintiffs' claims are based on an Oregon product liability law that provides for civil liability for "any failure to warn regarding a product." ORS 30.900. Essentially, plaintiffs assert that Pliva failed to adequately warn Ms. Phelps, her doctors, and the medical community in general that its product was dangerous and that long-term use could cause tardive dyskinesia. However, as discussed, the Supreme Court has held that all warnings-based claims against generic drug manufacturers are preempted by federal regulations - Pliva was not allowed to change its warning label, nor was it allowed to issue Dear Doctor letters to Ms. Phelps' physicians or the medical community in general. Therefore, all of plaintiffs' claims are preempted except for the recently added claim for failure to update the warning label in 2003 and 2004, and, except for that claim, defendant Pliva's motion to dismiss should be granted.

Plaintiffs' Motion for Partial Summary Judgment

Plaintiffs claim that they are entitled to summary judgment on three theories of defendants' negligence: (1) Pliva was negligent as a matter of law in failing to include FDA-approved warning information in its label for metoclopramide; (2) Pliva was negligent as a matter of law in failing to monitor the safety of its drug; and (3) Pliva and Northstar were negligent as a matter of law for failing to provide any warning to the medical community regarding their metoclopramide products.

Plaintiffs' first theory rests on the claim that Pliva failed to include changes to its warning label that were approved in 2003 and 2004, which would be a violation of FDA regulations' "ongoing

duty of sameness" as explained above. This may be a viable claim of negligence per se;[2] however, plaintiffs did not specifically allege this claim until November 22, 2011 when they filed their First Amended Complaint. Accordingly, Pliva has not had an adequate opportunity to respond to this claim, and summary judgment is not appropriate at this time. Thus, I recommend that this court deny plaintiffs' motion for summary judgment on this basis without prejudice.

FDA regulations preempt plaintiffs' second and third theories of liability. In support of the second theory, in which Pliva allegedly "failed to monitor the safety of its drug," plaintiffs claim that "the Mensing decision indicated that generic manufacturers are required to monitor the safety of their drug products once they enter the marketplace, and that federal law requires them to take certain action when it has concerns regarding the safety of its drug." In actuality, the Court assumed for the sake of argument that generic manufacturers have a duty to monitor their products and then petition the FDA to approve a stronger warning label if necessary, but the majority ultimately did not resolve the issue because it found preemption even assuming such a duty existed. Mensing, 131 S. Ct. at 2577. The Court reasoned that if a generic manufacturer can not "independently accomplish[] what state law requires," without relying on actions by the FDA, "it has established preemption." Id. at 2580. Likewise, here, even if Pliva had a duty to monitor its generic drug products, Pliva would still have had to petition the FDA and wait for the agency's approval before Pliva could change its

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[2] Oregon courts have held that "violations of statutory safety rules by themselves provide the element of negligence with respect to those risks that the rules are meant to prevent, at least unless the violator shows that his conduct in fact did not violate the rule under the circumstances." Axen v. Am. Home Products Corp., 158 Or. App. 292, 306-07 opinion adhered to as modified on reconsideration, 160 Or. App. 19 (1999). But see In re Trasylol Products Liab. Litig., 763 F. Supp. 2d 1312, 1330 (S.D. Fla. 2010) (disagreeing, and holding that "the FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with its provisions.")

warning labels.

Plaintiffs' third theory, as it relates to Pliva, rests on the same warnings-based claims that are preempted by FDA regulations, as identified in Mensing and discussed above. Plaintiffs' allege that Pliva "failed to provide any warning to the medical community regarding [its] metoclopramide products." However, as Pliva was not allowed to change its warning labels, nor was it allowed to issue Dear Doctor letters, Pliva's state-law duty to warn is preempted by federal regulations. Therefore, I recommend that this court deny plaintiffs' motion for summary judgment against Pliva.

Finally, as noted above, plaintiffs have not established that Northstar's metoclopramide product was the proximate cause of Ms. Phelps' injuries. Thus, I recommend that this court deny plaintiffs' motion for summary judgment against Northstar.

Conclusion

I recommend that this court grant defendant Northstar's motion for summary judgment. (#190). I recommend that this court grant defendant Pliva's motion to dismiss (#188) based on federal preemption. I recommend that this court deny plaintiffs' motion for partial summary judgment (#192) based on its assertions that Pliva was negligent for failing to monitor the safety of its drug and that Pliva and Northstar were negligent for failing to warn the medical community about their metoclopramide products. I recommend that plaintiffs' motion for summary judgment based on its claim that Pliva was negligent for failing to include the 2003 and 2004 updates to its warning labels be denied without prejudice.

If my Findings and Recommendations are adopted, this case will proceed on plaintiffs' claim against Pliva for its failure to update its warning labels in 2003 and 2004.

The above Findings and Recommendation will be referred to a United States District Judge

for review. Objections, if any, are due no later than fourteen days after the date this order is filed. The parties are advised that the failure to file objections within the specified time may waive the right to appeal the District Court's order. Martinez v. Ylst, 951 F.2d 1153 (9th Cir. 1991). If no objections are filed, review of the Findings and Recommendation will go under advisement on that date. If objections are filed, any party may file a response within fourteen days after the date the objections are filed. Review of the Findings and Recommendation will go under advisement when the response is due or filed, whichever date is earlier.

DATED this 30th day of November, 2011.

THOMAS M. COFFIN
United States Magistrate Judge